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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/336,103	06/18/1999	KAREN M. DOWNS	960296.95912	7263

26710 7590 03/14/2002

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MILWAUKEE, WI 53202-4497

EXAMINER

WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/14/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/336,103

Applicant(s)

DOWNS, KAREN M.

Examiner

Michael Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01/29/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13,15,16,18 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-13,15,16,18 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1632.

The marked up version does not have bracketing of the deleted references. Use of extensive underlining is confusing.

Applicant's arguments filed 1-29-02, paper number 13, have been fully considered but they are not persuasive.

### ***Election/Restriction***

This application contains claims 1-13, 15, 16 and 18 drawn to an invention nonelected in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 14, 17, 19, 20, 24-26 have been canceled. Claims 28 and 29 have been added.

Newly submitted claim 29 is directed to an invention that is independent or distinct from the invention originally claimed because it requires transgenic allantois tissue.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 29 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Claims 27 and 28 are under consideration as they relate to a method of observing vascularization in culture. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

1. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 is indefinite because it is dependent upon claim 25 which has been canceled. Nor would the limitation in claim 27 have antecedent basis in claims 28 or 29 if dependent therefrom. Clarification is required.

***Claim Rejections - 35 USC § 102***

2. Claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Downs (Downs et al., Feb. 1995, Development, Vol. 121, pages 407-416) for reasons of record.

Downs taught isolating allantoic tissue, culturing the tissue *in vitro*, transplanting the allantoic tissue to an embryo and observing the allantois, specifically observing the attachment of the allantois to the chorion (pg 408, col. 2; pg 409, col. 1, para. 1; pg 411, para. bridging col. 1 and 2). Treating allantoic tissue with a compound as claimed is equivalent to contacting the allantoic tissue with an embryo as taught by Downs. In addition, Downs treated the allantoises with [<sup>3</sup>H]methyl thymidine (page 408, col. 2, para. 3) and observ<sup>ed</sup>~~ing~~ the effect of [<sup>3</sup>H]methyl thymidine on growth and development (page 409, col. 1, line 14). Claim 27 is included because the dependency of the claim is unclear.

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Applicants argue Downs did not observe vascularization after administering [<sup>3</sup>H]methyl thymidine. Therefore, applicants argue Downs to not teach observing vascularization as claimed. If the argument is intended to mean [<sup>3</sup>H]methyl thymidine prevented vascularization, applicants argument is not persuasive because the claims encompass administering compounds that prevent vascularization. The claims do not require obtaining vascularization because the compound may prevent vascularization.

Applicants argue observing attachment of the allantois to the chorion is not “observing vascularization” because attachment of the allantois to the chorion is not necessary for vascularization. Applicants argue Downs did not observe vascularization; Downs merely observed growth of the allantoic tissue. Therefore, applicants argue Downs does not teach observing vascularization as claimed. Applicants arguments are not persuasive because observing growth of allantoic tissue is “observing vascularization,” because allantoic tissue becomes the umbilical chord which have blood vessels, and because attachment to the allantois to the chorion a step in the process of vascularization of the allantois (page 407, col. 2, 5 lines from the bottom).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



**MICHAEL C. WILSON**  
**PATENT EXAMINER**